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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

<p>ABRAXIS BIOSCIENCE, INC., Plaintiff, v. NAVINTA LLC, Defendant.</p>	<p>DOCUMENT FILED ELECTRONICALLY Civil Action No. 07-1251-JAP-TJB Hearing Date: August 18, 2008</p>
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**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S
MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION
DUE TO PLAINTIFF'S LACK OF STANDING**

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I. INTRODUCTION

Plaintiff Abraxis BioScience, Inc. did not possess the requisite title to any of the three patents asserted in this action and therefore lacked standing to sue for patent infringement at the time Plaintiff filed its Complaint on March 15, 2007. Prior to March 15, 2007, U.S. Patent No. 4,870,086 was owned by Astra Läkemedel Aktiebolag and U.S. Patent Nos. 5,670,524 and 5,834,489 were owned by AstraZeneca AB. On the day that Plaintiff filed the Complaint, the respective patent owners assigned all of their rights, title and interest in the asserted patents not to Plaintiff but to a third “Astra” entity, AstraZeneca UK Limited.

Because

plaintiff lacked title to the asserted patents and standing to sue at the inception of this lawsuit, and still lacks standing to sue for past infringements, Defendant Navinta LLC requests an Order dismissing Abraxis’ Complaint and First Amended Complaint.

II. LEGAL BACKGROUND

Federal Rule of Civil Procedure 12(b)(1) provides for the dismissal of action on the basis of lack of subject matter jurisdiction. Where, as here, a defendant seeks to dismiss a complaint for lack of subject matter jurisdiction, the plaintiff has the burden to provide subject matter jurisdiction by a preponderance of the evidence. *Toxgon Corp. v. BNFL, Inc.*, 312 F.3d 1379, 1383 (Fed. Cir. 2002). “An objection to standing is properly made on a Rule 12(b)(1) motion.” *Tasini v. New York Times Co., Inc.*, 184 F.Supp.2d 350, 354-355 (S.D.N.Y. 2002) *citing Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 88-89 (1998); *See also Mentor H/S, Inc. v.*

Medical Device Alliance, Inc., 240 F.3d 1016, 1018 (Fed. Cir. 2001) (The issue of whether a party “has sufficient rights in a patent to bring suit in its own name is jurisdictional”).

“If a party lacks title to a patent, that party has no standing to bring an infringement action under that patent.” *Lans v. Digital Equipment Corp.*, 252 F.3d 1320, 1328 (Fed. Cir. 2001) (affirming dismissal of complaint and denial of motion to amend pleadings to substitute patentee as plaintiff); 35 U.S.C. § 281 (“A patentee shall have remedy by civil action for infringement of his patent”). “[I]n order to assert standing for patent infringement, the plaintiff must demonstrate that it held enforceable title to the patent *at the inception of the lawsuit*.”

Paradise Creations, Inc. v. UV Sales, Inc., 315 F.3d 1304, 1309 (Fed. Cir. 2003); *see also Keene Corp. v. United States*, 508 U.S. 200, 207 (1993) (There is a “longstanding principle that the jurisdiction of the Court depends upon the state of things at the time of the action brought”).

A plaintiff that has no enforceable rights in the patent at the time it filed suit lacks a cognizable injury necessary to assert standing under Article III of the Constitution and such a defect in standing cannot be cured after the inception of the lawsuit. *Paradise Creations, Inc. v. UV Sales, Inc.*, 315 F.3d 1304, 1310 (Fed.Cir.2003). “[I]f the original plaintiff lacked Article III initial standing, the suit must be dismissed, and the jurisdictional defect cannot be cured.”

Schreiber Foods, Inc. v. Beatrice Cheese, Inc., 402 F.3d 1198, 1203 (Fed. Cir. 2005), *citing Paradise Creations, Inc. v. UV Sales, Inc.*, 315 F.3d 1304, 1309 (Fed.Cir.2003); *See, also, Church & Dwight Co., Inc. v. Abbott Laboratories*, No. 05-2142, 2006 WL 3000201, *5 (D.N.J. Oct. 20, 2006) (denying plaintiff’s motion to amend complaint to add party with standing, and granting cross-motion to dismiss patent infringement claim).

III. ARGUMENT

A. *The Complaint Must Be Dismissed Because Abraxis Lacked Title To The Asserted Patents At The Time The Complaint Was Filed*

On March 15, 2007, Plaintiff Abraxis BioScience, Inc. (“Abraxis”) filed its Complaint alleging infringement of U.S. Patent No. 4,870,086 (“the ‘086 patent”), U.S. Patent No. 5,670,524 (“the ‘524 patent”), and 5,834,489 (“the ‘489 patent”) (collectively “the Asserted Patents”). However, Abraxis did not have title to any of the Asserted Patents on March 15, 2007 and

Prior to filing the lawsuit, Abraxis entered into an Asset Purchase Agreement with AstraZeneca UK Limited on April 26, 2006 whereby it was agreed that AstraZeneca UK Limited “shall, or shall cause one or more of its Affiliates to, Transfer to the Purchaser, and the Purchaser shall purchase and accept from the Seller or its Affiliates, as applicable, all of the right, title and interests of the Seller and its Affiliates in” certain assets that included each of the Asserted Patents. Declaration of Benjamin J. Lehberger In Support Of Defendant’s Motion to Dismiss For Lack of Subject Matter Jurisdiction (“Lehberger Decl.”), Ex. A, p. 15; . The actual transfer of the Asserted Patents was to occur in the future by means of a separate “IP Assignment Agreement” “in the form to be mutually agreed upon by the parties prior to a July 31, 2006 closing date.” Lehberger Decl., Ex. A, p. 7;

At the time, Astra Läkemedel Aktiebolag still owned the ‘086 patent

and AstraZeneca AB still owned the '524 patent and the '489 patent. Lehberger Decl., Ex. D – F.

If on the date of a purported assignment the assignor had nothing to assign, the purported assignment is a nullity. *RAD Data Communications, Inc. v. Patton Electronics Co.*, 882 F.Supp. 351, 353 (S.D.N.Y. 1995) (holding that a purported assignment executed two days prior to the assignor obtaining title in the patent was a nullity and dismissing purported assignee's patent infringement lawsuit) *citing FilmTec Corp. v. Allied-Signal, Inc.*, 939 F.2d 1568, 1572 (Fed. Cir. 1991). Thus, title to the Asserted Patents

remained with Astra Läkemedel Aktiebolag and AstraZeneca AB.

On March 15, 2007, the day that Abraxis filed its Complaint, Astra Läkemedel Aktiebolag and AstraZeneca AB assigned their respective rights, title and interest in the Asserted Patents to AstraZeneca UK Limited ("March 2007 Assignments"). Lehberger Decl., Ex. G – H.

The chains of title for each of the Asserted Patents are illustrated as follows, including the purported assignments by AstraZeneca UK Limited at a time when AstraZeneca UK Limited had no rights to assign.

Chain of title for U.S. Patent 4,870,086:



Chain of title for U.S. Patent Nos. 5,670,524 and 5,834,489:



As illustrated, Abraxis lacked title to the Asserted Patents at the time the Complaint was filed on March 15, 2007 and for a substantial period of time during this case. Without legal title to the Asserted Patents, Abraxis had no standing to bring this infringement action. *Lans v. Digital Equipment Corp.*, 252 F.3d 1320, 1328 (Fed. Cir. 2001). Navinta therefore respectfully requests that this Court dismiss each of Abraxis' claims for infringement of the Asserted Patents.

B. Abraxis' Lack of Standing To Bring This Action Cannot Be Cured By A Subsequent Assignment Of The Asserted Patents To Abraxis

The case law is overwhelming that “if the original plaintiff lacked Article III initial standing, the suit must be dismissed, and the jurisdictional defect cannot be cured by the addition of a party with standing, nor by the subsequent purchase of an interest in the patent in suit.” *Schreiber Foods, Inc. v. Beatrice Cheese, Inc.*, 402 F.3d 1198, 1203 (Fed. Cir. 2005), *citing Paradise Creations, Inc. v. U V Sales, Inc.*, 315 F.3d 1304, 1309 (Fed.Cir.2003) and *Gaia Techs., Inc. v. Reconversion Techs., Inc.*, 93 F.3d 774, 780 (Fed.Cir.1996); see, also, *Church & Dwight Co., Inc. v. Abbott Laboratories*, No. 05-2142, 2006 WL 3000201, *5 (D.N.J. Oct. 20, 2006) (denying plaintiff’s motion to amend complaint to add party with standing, and granting cross-motion to dismiss patent infringement claim).

RAD Data Communications, Inc. v. Patton Electronics Co., 882 F.Supp. 351, 353 (S.D.N.Y. 1995) *citing FilmTec Corp. v. Allied-Signal, Inc.*, 939 F.2d 1568, 1572 (Fed. Cir. 1991). Furthermore, “*nunc pro tunc* assignments are not sufficient to confer retroactive standing.” *Enzo APA & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998) (vacating judgment of infringement because plaintiff lacked standing to assert

infringement claim where no written transfer of rights under patent had been made at time claims were brought).

Assignments of patents must also be in writing. 35 U.S.C. § 261; *Enzo APA & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998). Therefore, despite whether anyone “considered” Abraxis to be the owner of Asserted Patents at the time the Complaint was filed or any time prior thereto, there was no valid written assignment to this effect. In fact, all written assignments concerning the Asserted Patents clearly indicate that Abraxis did not have title to the Asserted Patents at the time the Complaint was filed and thus Abraxis lacked standing to bring this action. Lehberger Decl., Ex. G – H.

C. Abraxis' Lack of Standing To Bring This Action Was Not Cured By The Filing Of Abraxis' Amended Complaint

1. Filing An Amended Complaint Cannot Cure A Lack of Initial Standing

On November 20, 2007, , Abraxis filed an Amended Complaint including Counts I – III alleging infringement of the Asserted Patents. First Amended Complaint (Dkt. 53). Despite what may have been a delayed attempt by Abraxis to cure its lack of standing, the “initial standing of the original plaintiff is assessed at the time of the original complaint, even if the complaint is later amended.” *Schreiber Foods, Inc. v. Beatrice Cheese, Inc.*, 402 F.3d 1198, FN3 (Fed. Cir. 2005). Therefore, because Abraxis lacked initial standing, the suit must be dismissed. *Id.* at 1203.

2. Abraxis Was Not Granted Rights To Sue For Past Infringements And Therefore Still Lacked Standing At The Time The Amended Complaint Was Filed

Even if transferred title to the Asserted Patents to

Plaintiff Abraxis before the Amended Complaint was filed, Abraxis still did not have standing at the time of the Amended Complaint, and still to this day lacks standing, to bring a claim against Navinta for infringement under 35 U.S.C. § 271(e)(2)(A).¹ The act of infringement alleged by Abraxis to have been committed by Navinta – the filing of an Abbreviated New Drug Application (“ANDA”) under 21 U.S.C. 355(j) – occurred in 2006 and long before Abraxis obtained any rights in the Asserted Patents. First Amended Complaint (Dkt. 53), ¶¶ 17, 27, 41. Moreover, Abraxis does not have the right to sue for past infringements.

An assignment of a right of action for past infringements “must be express, and can not be inferred from an assignment of the patent itself.” *Arachnid, Inc. v. Merit Industries, Inc.*, 939 F.2d 1574, 1579 (Fed. Cir. 1990) *citing Moore v. Marsh*, 74 U.S. 515, 522 (1868) (“it is a great mistake to suppose that the assignment of a patent carries with it a transfer of the right to damages for an infringement committed before such assignment”).

Lehberger Decl. ¶ 11 states that Lehberger did not expressly transfer rights to sue for past infringements of the Asserted Patents to Plaintiff Abraxis. Lehberger Decl., Ex. I. Furthermore, even if it had, the assignor took title to the Asserted Patents on the day the Complaint was filed and likewise was never granted rights to sue for any past infringements that occurred prior to this lawsuit. Lehberger Decl., Ex. G – H.

Thus, even if Abraxis owned the Asserted Patents at the time the Amended Complaint was filed, Abraxis’ Complaint and Amended Complaint must be dismissed

¹ 35 U.S.C. § 271(e)(2)(A) states that “It shall be an act of infringement to submit” “an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent”).

because Abraxis lacked standing at the time the Complaint was filed and still now lacks standing to sue for any acts of infringement that occurred in the past, including the act of infringement alleged to have been committed when Navinta filed its ANDA in 2006.

D. *Navinta Will Be Substantially Prejudiced If Abraxis' Complaint And Amended Complaint Are Not Dismissed*

In *Enzo APA & Son, Inc. v. Geapag A.G.*, the Federal Circuit remarked on the implications of allowing a party to initiate a patent infringement action before obtaining title to the patent:

As a general matter, parties should possess rights before seeking to have them vindicated in court. Allowing a subsequent assignment to automatically cure a standing defect would unjustifiably expand the number of people who are statutorily authorized to sue. Parties could justify the premature initiation of an action by averring to the court that their standing through assignment is imminent. Permitting non-owners and licensees the right to sue, so long as they eventually obtain the rights they seek to have redressed, would enmesh the judiciary in abstract disputes, risk multiple litigation, and provide incentives for parties to obtain assignment in order to expand their arsenal and the scope of litigation. Inevitably, delay and expense would be the order of the day.

Enzo APA & Son, Inc. v. Geapag A.G., 134 F.3d 1090, 1093-94 (Fed. Cir. 1996), citing *Procter & Gamble Co. v. Paragon Trade Brands, Inc.*, 917 F.Supp. 305, 310 (D.Del. 1995).

In the context of an ANDA case such as this one, the implications are far more prejudicial because the timely commencement of a patent infringement action under the Hatch Waxman Act triggers an automatic 30 month stay of FDA approval of the defendant's ANDA.

35 U.S.C. § 271(e)(2)(A) "creates a highly artificial act of infringement that consists of submitting an ANDA" containing a Paragraph IV certification. *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Approval of an ANDA containing a Paragraph IV certification "may become effective immediately only if the patent owner has not initiated a lawsuit for infringement within 45 days of receiving notice of the certification." *Id.* at 677-678. "If the

owner brings such a suit, then approval may not be made effective until the Court rules that the patent is not infringed or until the expiration of (in general) 30 months, whichever first occurs.” *Id.*; 21 U.S.C. § 355(j)(4)(B)(iii).

Defendant Navinta filed its ANDA with a Paragraph IV certification concerning the ‘086 patent and sent notification to Abraxis and also to AstraZeneca entities in Sweden and the United States.² Abraxis then filed its Complaint for infringement of the ‘086 patent, as well as two other patents that were not the subject of a Paragraph IV certification, alleging to be the “owner of all rights, title and interest in and to the ‘086 patent, the ‘524 patent, and the ‘489 patent, including the right to sue and recover for patent infringement.” Complaint (Dkt. 1), ¶ 11. However, at the time of the Complaint and , Abraxis did not own the Asserted Patents. Thus, because Abraxis did not own the ’086 patent that was the subject of Navinta’s Paragraph IV certification at the time the Complaint was filed, and the actual patent owner failed to file bring a timely action for patent infringement. Therefore, Navinta’s ANDA should never have been subject to a 30-month stay of FDA approval.

Allowing a plaintiff to file an infringement suit under the Hatch-Waxman Act when they do not own the patent not only subjects the defendant to an improperly commenced lawsuit, as it would in a traditional patent infringement lawsuit, but also improperly subjects the defendant to a 30-month stay of FDA approval and prevents non-infringing generic alternative drugs from entering the marketplace. An Order from this Court dismissing Abraxis’ claims will allow for the 30-month stay of FDA approval of Navinta’s ANDA to be terminated. While the correct owner of the Asserted Patents may file a new action against Navinta at a later date, subject to

² Because Astra and Zeneca merged in 1999, Navinta sent notification for Astra Läkemedel Aktiebolag of Södertälje, Sweden to the General Counsel for AstraZeneca AB in Södertälje, Sweden, as well as the General Counsel for AstraZeneca LP and AstraZeneca Pharmaceuticals LP in the United States.

establishing subject matter jurisdiction, Abraxis' premature filing of a Complaint without standing should not be recognized and awarded with a continued stay of FDA approval of Navinta's ANDA to which Abraxis was never entitled. To permit this action to be maintained will encourage plaintiffs to file premature lawsuits to get the 30-month stay and worry about obtaining proper ownership of the patent later.

Navinta therefore respectfully requests that this Court dismiss each of Abraxis' Complaint and Amended Complaint.

E. *Navinta Should Be Awarded Attorneys Fees Due To Abraxis' Filing And Continued Prosecution Of This Lawsuit Without Standing And Abraxis' Failure to Produce Ownership Documents*

Court's may award attorney fees to the prevailing party in exceptional cases. 35 U.S.C. § 285. "The determination of whether a case is exceptional and, thus, eligible for and warranting an award of attorney fees under § 285 is a two-step process in which the district court must (1) determine whether there is clear and convincing evidence that a case is exceptional and (2) if so, then determine in its discretion whether an award of attorney fees is justified." *Digeo, Inc. v. Audible, Inc.*, 505 F.3d 1362, 1366-1367 (Fed. Cir. 2008).

A case may be found exceptional where there could not possibly be a reasonable ground for patent infringement because the plaintiff lacked legal title to the patent. *Digeo, Inc. v. Audible, Inc.*, 505 F.3d 1362, 1369 (Fed. Cir. 2008) (extending 35 U.S.C. § 285 case law to apply to situations where there could not possibly be a reasonable ground for patent infringement if there is no legal title to the patent, but affirming denial of attorney fees because there was no wrongful intent or gross negligence by plaintiff in not learning of a title defect). "The pertinent

inquiry here is whether [the plaintiff] knew or should have known its legal title was defective.”

Id.

A check of the U.S. Patent Office assignment records prior to Abraxis filing its Complaint would have revealed that AstraZeneca UK Limited likely did not have any rights in the Asserted Patents to assign to Abraxis .

Lehberger Decl, Ex. J – L. Each of the Asserted Patents was then assigned to AstraZeneca UK Limited on March 15, 2007. Lehberger Decl, Ex. G – H. Though it is difficult to imagine that Abraxis was not aware of these transfers that occurred on the day its Complaint was filed, Abraxis certainly became aware of its lack of title early on in this lawsuit.

Navinta alleged that “Abraxis is not the owner of any asserted patent and Abraxis lacks standing to bring and maintain this lawsuit” on May 7, 2007 in Navinta’s Answer, Defenses And Counterclaims To Complaint Of Abraxis BioScience, Inc. (Dkt. 5, “Navinta’s Answer”). A few months later, on August 14, 2007, the very law firm representing Abraxis in this lawsuit at the time recorded assignments in the U.S. Patent Office evidencing the March 2007 Assignments of the Asserted Patents to a third party, AstraZeneca UK Limited. Lehberger Decl, Ex. J – L.

On November 1, 2007, Navinta served a request for production calling for “All documents concerning the ownership, assignment and/or licensing of any rights in any of the Asserted Patents, including but not limited to all documents concerning any transfer or assignment of rights in any Asserted Patent to which AstraZeneca or Abraxis BioScience, Inc. was a party.” Lehberger Decl., Ex. M, Request No. 8.

. Yet, Abraxis failed to produce

or any other documents responsive to Navinta's request for production for the next sixth months.

On December 24, 2007, in response to Abraxis' First Amended Complaint, Navinta again alleged that "none of the asserted patents lists Abraxis as assignee" and "Upon information and belief, the '086 patent, the '524 patent, and the '489 patent are owned by 'AstraZeneca UK Limited' by way of an assignment recorded in the U.S. Patent Office on August 14, 2007." (Dkt. 64, pp. 2, 6).

On February 20, 2008, after Abraxis continued failure to produce any documents responsive to Navinta's request, and after a subsequent change of counsel, Navinta wrote to Abraxis' new counsel raising the issue of Abraxis' failure to produce documents concerning the ownership, assigning and/or licensing of any rights in any of the Asserted Patents. Lehberger Decl., Ex. N. Despite several follow up letters by Navinta, Abraxis failed to produce any documents response to Navinta's request or even respond to this and many other deficiencies noted in the February 20, 2008 letter.

On April 7, 2008, Navinta addressed the of Abraxis lack of title to the Asserted Patents in Navinta's Opposition to Abraxis' Motion to Dismiss Navinta's Counterclaims. (Dkt. 92, p. 7). On May 7, 2008, Navinta again wrote to Abraxis' counsel and specifically asked Abraxis to provide the ownership documents explaining that Abraxis' continued failure to do so raises serious questions as to whether Abraxis has standing in this lawsuit. Lehberger Decl., Ex. O. Finally, on May 14, 2008, over six months after Navinta's request for ownership and assignment documents, Abraxis produced ownership documents that are the subject of this motion. Lehberger Decl., Ex. P.

Based on the above, Navinta submits that Abraxis knew or at least should have known that it lacked title to the Asserted Patents at the time of the Complaint, and certainly became aware of its lack of title early on in this lawsuit. Navinta believes that an award of attorney fees is justified particularly in view of the evidence of Abraxis' knowledge, and Abraxis' failure to produce documents showing Abraxis' lack of title to the Asserted Patents for over six months while at the same time trying to correct the problem during the pendency of this lawsuit.

For these reasons, Navinta respectfully requests that this Court award Navinta its attorney's fees in defending this action or at least for the filing of this motion.

IV. CONCLUSION

For the foregoing reasons, Navinta respectfully requests that this Court dismiss Abraxis' Complaint and Amended Complaint, and award Navinta its attorneys' fees.

Respectfully submitted,

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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S
MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION
DUE TO PLAINTIFF'S LACK OF STANDING**

is to be electronically filed. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

July 16, 2008

Date

/s/Eric I Abraham

Eric I. Abraham